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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/109,864 | 07/06/1998 | JIAN NI | PF354P1 | 4016 |

22195 7590 03/20/2002

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ROCKVILLE, MD 20850

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| EXAMINER |
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ULM, JOHN D

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| ART UNIT | PAPER NUMBER |
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1646

OATE MAILED: 03/20/2002

26

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/109,864

Applicant(s)
Ni et al.

Examiner
John Ulm

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1646



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (e). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 14, 2002
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 D.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-41, 43, 66-93, 95, 106-110, 112-125, 127-153, and 158-177 is/are pending in the application.
- 4a) Of the above, claim(s) 66, 69, 72-74, 158, 160-171, and 175-177 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-41, 43, 67, 68, 70, 71, 75-93, 95, 106-110, 112-125, 127-153, 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 25 20) ☐ Other:

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1) Claims 29 to 41, 43, 66 to 93, 95, 106 to 110, 112 to 125, 127 to 153 and 158 to 177 are pending in the instant application. Claims 66, 69, 72 to 74, 121, 136 and 145 have been amended, claims 44 to 65 and 154 to 157 have been canceled and claims 158 to 177 have been added as requested by Applicant in Paper Number 24, filed 14 January of 2002.

2) Claims 66, 69, 72 to 74, 158, 160 to 171 and 175 to 177 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 13.

3) A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 14 January of 2002 has been entered.

4) Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

5) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6) Claims 29 to 41, 43, 67, 68, 70, 71, 75 to 93, 95, 106 to 110, 112 to 125, 127 to 153, 159 and 172 to 174 are rejected under 35 U.S.C. § 101 because they are drawn to an invention with no apparent or disclosed specific and substantial credible utility for those reasons

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of record as applied to claims 29 to 41, 43 to 93, 95 and 105 to 153 in section 7 of Paper Number 15.

Applicant's traversal of this rejection essentially repeats those arguments of record. Applicant urges that the instant specification asserts that the protein of the instant invention is useful "as a cancer diagnostic and/or therapeutic". This asserted utility is not credible. A credible utility is one which an artisan of ordinary skill would believe more likely than not to be true. An artisan of ordinary skill in the art of molecular biology would not believe that a protein of the instant invention is involved in cancer simply because there is absolutely no evidence of record that supports such a conclusion. The instant specification, especially at pages 38 through 47, makes numerous incredible assertions of utility of the instant protein in the diagnosis and treatment of virtually all of the diseases known to mankind, including various bacterial and viral infections. These assertions are incredible because there is no evidence or sound scientific reasoning to support them. In fact, at least one of the asserted utilities is in direct conflict with the facts of record. The text bridging pages 46 and 47 of the instant specification teaches that the Galactin 11 protein of the instant invention can be administered exogenously to an individual for the purpose of stimulating hemopoiesis. This assertion is not believable simply because the only activity which has been demonstrated for this protein is the ability to induce apoptosis (programme cell death) when over-expressed in a cell line, as described in Example 5 of the instant specification. One would not conclude that a protein which causes apoptosis is also going

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to induce cell proliferation in the complete absence of evidence of this property since these two properties appear to be mutually exclusive.

Applicant has essentially argued that it is the responsibility of the Examiner to prove that the claimed invention is without utility. The Examiner is under no obligation to prove a negative, the examiner must simply provide sound reasoning in support of a conclusion that an element is lacking from a specification, and this has been done. In the instant case, it is the responsibility of Applicant to disclose a credible utility for the claimed invention and factually unsupported assertions like those presented on pages 33 through 41 of the instant specification are so incredible on their face that they need not be "proven" wrong.

7) Claims 29 to 41, 43, 67, 68, 70, 71, 75 to 93, 95, 106 to 110, 112 to 125, 127 to 153, 159 and 172 to 174 stand also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

8) Applicant's arguments filed 14 January of 2002 have been fully considered but they are not persuasive for those reasons given above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.


Official papers filed by fax should be directed to (703) 308-4242 or (703) 872-9306. Official responses under 37 C.F.R. § 1.116 should be directed to (703) 872-9307.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.


JOHN ULM
PRIMARY EXAMINER
GROUP 1800